**INSTRUCTIONS FOR USE**

**MERDECALIN**

**DESCRIPTION**

MERDECALIN is a perfluorocarbon liquid for intraocular application. It is purified, sterile and non-pyrogenic. Does not contain latex and phthalates.

**PACKAGING**

The liquids are packaged in glass vials and syringe. Products that are packed in vials are sealed with a polymer plug and a metal cap. The products in vial are presented with a single use needle and syringe. Quantity is indicated on the pack.

**STERILIZATION METHOD**

Products are sterilized in their final package which includes a sterilized pouch to guarantee sterility of the contents and steam sterilization.

**PHYSICAL PROPERTIES**

| PARAMETERS | MERDECALIN |
|---|---|
| Composition | Perfluorodecaline (95-100%) |
| Density | 1.94 |
| Refractive Index | 1.31 |
| Viscosity | 2.7 |
| Interfacial Tension | 17.6 mN/m |
| Boiling Point | 142°C |

**INDICATIONS**

MERDECALIN is used as a per-operative device, for transitory intra-ocular endotamponade. In particular retinal detachment (RD), RD with giant tear, RD with proliferative vitreal retinopathy (PVR) including diabetic proliferative retinopathy, retrieval of luxated natural or artificial lens in the vitreous.

**CONTRA - INDICATIONS**

The product should not be allowed to infiltrate under the sub-retinal tissues since there are no specific studies on tolerance.

**SIDE EFFECTS**

If MERDECALIN is not completely removed after intraocular surgery, retinal damage and toxidity can occur due to its high specific gravity.

**INSTRUCTIONS FOR APPLICATION**

MERDECALIN are restricted for use by surgeons trained in retinal surgery. Products are per-operative devices for vitreoretinal surgery. It should not be left in place in the eye at the end of procedure. Do not use a glass syringe under any conditions. The volume injected must be adapted to each procedure. Fit the needle onto the syringe and pierce the stopper after having removed the metal cap. Transfer the product from the vial into the syringe. Replace the needle with a cannula for intra-vitreous injection. Inject MERDECALIN slowly and progressively just in front of the tear, after total pars plana vitrectomy. Attention to also be taken to maintain the tip of cannula inside the bubble during injection and just in front of the retinal tear. This will prevent the product from dispersing and infiltrating the sub-retinal tissues. If despite this precaution, dispersion occurs, the droplets will spontaneously regroup into the principal MERDECALIN bubble, or can be removed to an extrusion cannula. Use a fluid or gas exchange procedure to remove the product.

**WARNING**

The product must be used only by professional persons in aseptic areas.
This device is for single use only.
DO NOT REUSE OR RESTERILIZE.
Do not use this device if package is damaged or opened.
Never use a device if it is beyond its expiration date.

**DISPOSAL**

Dispose of used products in accordance with established hospital protocol for hazardous waste.

**Symbols used on packaging and label**

| Symbols and Description | | | |
|---|---|---|---|
| MERAN | Company logo | | Do Not Sterilize The Second Time |
| Product Name/Model | Product Name | | Do Not Expose to Direct Sunlight |
| CE 2292 | Notified Body Number | | Keep Away From Contact With Water |
| | See User Manual | | Keep at the Specified Temperature Range |
| Rx | Should Be Used By An Expert | REF | Reference Number |
| LOT XXXXXXX | Lot Number | | Barcode Number |
| XXXXXX | Production Date | | Do Not Use if the Package is Damaged |
| TF05.LBXX/R01/23.09.2020 | Label Information | | Expiration Date |
| STERILE | Sterilized with Steam. | %70 | Keep at the Specified Humidity Range |
| | Single Use | | Manufacturer Information |

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